Filing Date: September 30, 2003

Title: DRUG-ELUTING ELECTRODE

IN THE CLAIMS

Please amend the claims as follows:

- 1. (Currently Amended) An apparatus comprising:
- an electrical lead comprising a lead body and an electrical conductor; and an electrode coupled to the electrical conductor, wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including two or more layers, with a first layer adjacent the surface of the electrode including an insulative material and a second layer adjacent the first layer and not adjacent to the surface of the electrode including at least one pharmacological agent.
- 2. (Original) The apparatus of claim 1, wherein the electrode includes a helical tip.
- 3. (Original) The apparatus of claim 1, wherein the pharmacological agent comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 4. (Original) The apparatus of claim 3, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
- 5. (Original) The apparatus of claim 1, wherein the first layer comprises a polymeric base coat on the electrode surface and the second layer comprises a matrix including a polymer and at least one pharmacological agent, wherein the second layer at least partially covers the polymeric base coat.
- 6. (Original) The apparatus of claim 5, wherein the pharmacological agent comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

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- 7. (Original) The apparatus of claim 6, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
- The apparatus of claim 5, wherein the polymeric base coat is ethylene vinyl 8. (Original) alcohol.
- The apparatus of claim 1, further comprising a third layer above the second layer, 9. (Original) wherein the third layer includes a porous barrier.
- 10. (Original) The apparatus of claim 9, wherein the porous barrier comprises a polymeric coating.
- The apparatus of claim 9, wherein the second layer comprises a 11. (Currently Amended) matrix including a polymer and at least one pharmacological agent and the third layer regulates the release of the pharmacological agent from the second layer matrix.
- 12. (Original) The apparatus of claim 1, further comprising an outer layer, wherein the outer layer includes at least one pharmacological agent.
- 13. (Original) The apparatus of claim 12, wherein the pharmacological agent comprises an antiarrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 14. (Original) The apparatus of claim 13, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
- 15. (Original) The apparatus of claim 1, wherein the first layer is adapted to functionally increase an impedance of the electrode.

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16. (Previously Presented) A system comprising:

an electrical pulse generator;

an electrical lead releasably coupled to electrical pulse generator, wherein the electrical lead includes a lead body and an electrical conductor; and

an electrode coupled to the electrical conductor, wherein an outer surface of the electrode is coated with two or more layers comprising a first layer including an insulative material and a second layer over the first layer, the second layer including at least one pharmacological agent.

- 17. (Original) The system of claim 16, wherein the electrode includes a helical tip.
- 18. (Original) The system of claim 16, wherein the pharmacological agent comprises an antiarrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 19. (Original) The system of claim 18, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
- 20. (Original) The system of claim 18, wherein the anti-inflammatory agent is dexamethasone.
- 21. (Previously Presented) The system of claim 16, wherein the first layer comprises a polymeric base coat on the electrode surface and the second layer comprises a polymer and at least one pharmacological agent matrix on the polymeric base coat.
- 22. (Original) The system of claim 21, wherein the pharmacological agent comprises an antiarrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 23. (Original) The system of claim 22, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.

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24. (Original) The system of claim 21, wherein the polymeric base coat is ethylene vinyl alcohol.

- 25. (Original) The system of claim 21, further comprising a third layer, wherein the third layer comprises a porous barrier.
- 26. (Original) The system of claim 25, wherein the third layer regulates the release of the pharmacological agent from the matrix.
- 27. (Original) The system of claim 25, further comprising a fourth layer, wherein the fourth layer comprises at least one pharmacological agent.
- 28. (Original) The system of claim 27, wherein the pharmacological agent of the fourth layer comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 29. (Original) The system of claim 28, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
- 30. (Previously Presented) An apparatus comprising:

an electrical lead comprising a lead body and an electrical conductor; and an electrode coupled to the electrical conductor, wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including three or more layers, with an inner layer including a pharmacological agent in a polymer matrix for regulated, chronic release of the pharmacological agent and an outer layer including only a pharmaceutical agent such that the pharmaceutical agent of the outer layer is exposed to tissue upon implant of the electrode, and a middle layer between the inner layer and the outer layer, the middle layer including a porous polymer barrier.

31. (Original) The apparatus of claim 30, wherein the electrode includes a helix.

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32. (Original) The apparatus of claim 30, further including a third layer directly adjacent a surface of the electrode comprising a polymer primer layer, with the inner layer adjacent the polymer primer layer.

- 33. (Original) The apparatus of claim 30, wherein the pharmaceutical agent in the polymer matrix includes an anti-inflammatory drug.
- 34. (Original) The apparatus of claim 30, wherein the pharmaceutical agent in the polymer matrix includes an anti-proliferative drug.
- A method comprising: 35. (Currently Amended)

coating an electrode with a first layer, wherein the first layer comprises a polymeric base coat; and

coating the first layer of the electrode with a second layer, wherein the second layer comprises a polymer and at least one pharmacological agent, and at least partially coats the first layer.

- 36. (Original) The method of claim 35, wherein the pharmacological agent comprises an antiarrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 37. (Original) The method of claim 36, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
- 38. (Original) The method of claim 35, wherein the polymeric base coat is ethylene vinyl alcohol.
- 39. (Original) The method of claim 35, further comprising a third layer, wherein the third layer comprises a porous barrier.

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The method of claim 39, wherein the second layer comprises a 40. (Currently Amended) matrix including a polymer and at least one pharmacological agent and the third layer regulates the release of the pharmacological agent from the second layer matrix.

- 41. (Original) The method of claim 35, further comprising an outer layer, wherein the outer layer comprises at least one pharmacological agent.
- 42. (Original) The method of claim 41, wherein the pharmacological agent comprises an antiarrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an anti-proliferative agent, or a combination thereof.
- 43. (Original) The method of claim 42, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
- The method of claim 35, wherein the coating is applied by 44. (Previously Presented) contacting the exterior of the electrode with a composition comprising at least one polymer and at least one pharmacological agent.
- 45. (Original) The method of claim 44, wherein the contacting includes spraying.